UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

RICHARD RICE, AS TRUSTEE OF THE RICHARD E. AND MELINDA RICE REVOCABLE FAMILY TRUST 5/9/90, and CHRISTIAN STANKEVITZ, Individually and On Behalf of All Others Similarly Situated, Plaintiff, v. INTERCEPT PHARMACEUTICALS, INC., MARK PRUZANSKI, and SANDIP S. KAPADIA, Defendants.	Case No. 1:21-cv-00036-LJL

PLAINTIFFS' CORRECTED[1] FIRST AMENDED COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS

[1] Corrected ***only*** as to replace the initial plaintiff with the Court-appointed lead plaintiff and additional plaintiff in the Caption of the document.

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1. Lead Plaintiff Richard Rice, as Trustee of the Richard E. and Melinda Rice Revocable Family Trust 5/9/90 ("Lead Plaintiff") and plaintiff Christian Stankevitz (together, "Plaintiffs"), individually and on behalf of all others similarly situated, by and through their attorneys, hereby bring this complaint against defendants Intercept Pharmaceuticals, Inc. ("Intercept" or the "Company"), Mark Pruzanski ("Pruzanski"), and Sandip Kapadia ("Kapadia") (collectively, "Defendants"). The allegations herein are based on Plaintiffs' personal knowledge as to their own acts and on information and belief as to all other matters, such information and belief having been informed by the investigation conducted by and under the supervision of their attorneys, which includes a review of, without limitation: U.S. Securities and Exchange Commission ("SEC") filings by Intercept; securities analysts' reports and advisories about the Company; press releases and other public statements issued by and disseminated by the Company; media reports about the Company; information readily obtainable on the Internet and from other sources deemed reliable; and interviews of former employees of Intercept and other persons with knowledge of the matters alleged herein. Plaintiffs' attorneys' investigation into the matters alleged herein is ongoing and many relevant facts are known only to, or are exclusively within the custody or control of, the Defendants. Plaintiffs believe that substantial additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery. On behalf of themselves and the class they seek to represent, Plaintiffs allege as follows:

I. NATURE OF THE ACTION

2. This is a securities class action on behalf of a class consisting of all persons and entities that purchased or otherwise acquired Intercept securities between September 27, 2019 and October 8, 2020, inclusive (the "Class Period"), seeking to recover damages caused by Defendants' violations of §§ 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act") and Rule 10b-5 promulgated thereunder.

3. Intercept is a biopharmaceutical company focused on the development and commercialization of novel therapeutics to treat progressive non-viral liver diseases.

4. The Company has one drug, obeticholic acid or "OCA," which has been approved by the FDA and brought to market for the treatment of primary biliary cholangitis ("PBC"), a liver disease that leads to the progressive destruction of the bile ducts in the liver. OCA is branded under the name Ocaliva.

5. Since PBC is a relatively rare liver disease with a small market of patients, the Company sought to have OCA, the same drug, approved as a treatment for nonalcoholic steatohepatitis ("NASH"), a liver disease that impacts tens of millions of potential patients and has no approved drug treatments. However, prior to submitting the New Drug Application ("NDA") to the U.S. Food and Drug Administration ("FDA") for the treatment of NASH with OCA, Defendants became aware of several serious adverse events from OCA in PBC patients that were not already cited on Ocaliva's label (*i.e.*, risks that were not previously addressed or not known about and previously addressed by the FDA).

6. In spite of these adverse events from the same drug impacting the same organ (the liver), the Company went forward with the NDA (and even sought accelerated approval)—for which the FDA would have to balance the efficacy and safety of the drug—without disclosing the material risk to approval from these adverse events.

7. As a result of the serious adverse events, the FDA informed Defendants in May 2020 that they had identified a Newly Identified Safety Signal ("NISS") with Ocaliva related to liver disorder and were going to investigate the risk. The Company did not disclose this fact.

8. Soon thereafter, on May 22, 2020, the FDA notified Defendants that it was postponing the advisory committee at which the NDA would have been reviewed to allow for the review of additional data the agency had requested. Defendant Pruzanski represented, however, that the Company was engaged in a dialogue with the FDA and that "we believe that the additional data being submitted will be important in facilitating a more informed discussion at the AdCom" and "We remain confident in our NDA submission."

9. On this news, the Company's share price fell $11.18, or 12.19%, to close at $80.51 per share on May 22, 2020, on unusually heavy trading volume.

10. Thereafter, on June 29, 2020, the Company disclosed that FDA had provided a complete response letter – an effective refusal to approve the drug for NASH. The Company explained that, based on the data the FDA had reviewed to date, the FDA had determined that the predicted benefit of OCA based on a surrogate histopathologic endpoint remains uncertain and does not sufficiently outweigh the potential risks to support accelerated approval for the treatment of patients with liver fibrosis due to NASH.

11. On this news, the Company's share price fell $30.79, or 39.73%, to close at $46.70 per share on June 29, 2020, on unusually heavy trading volume.

12. Even after receiving the complete response letter, the Company did not come clean about the NISS. After not mentioning it at all for months, Defendants then attempted to bury it by inserting language about the safety signal in the middle of boilerplate paragraphs that address an unrelated subject on pages 57 and 64 of the Company's August 10, 2020 quarterly report. Intercept also did not address it in either the Company's corresponding press release announcing its quarterly results or the earnings call. This strategy was actually successful because no one, including analysts, noticed the comment buried deep in the boilerplate disclosures.

13. It was not until months later that someone noticed the change and tweeted about it. Even then it took an article published on October 8, 2020, noting the tweet and the change, for the market to realize that the FDA was investigating the NISS and that the timing and subject matter of the investigation appeared to be related to the denial of the NASH NDA. As the article explained:[2]

> ***Intercept has not previously said anything publicly about the FDA examination. Instead, the company chose to disclose the inquiry by adding several new sentences to an existing risk-statement paragraph on the 57th page of its most recent quarterly report filed with the Securities and Exchange Commission.*** The change was picked up by a health care investor on Twitter earlier this week.

[2] All emphasis is added unless otherwise stated.

> In the same SEC filing, ***Intercept warned any safety concern associated with Ocaliva, "perceived or real," could negatively impact the drug's sales or its effort to expand use into other types of liver disease.***
>
> ***
>
> ***Did the FDA's liver safety evaluation of Ocaliva, which began in May, contribute to the agency's decision in June to reject the NASH application?***

14. On this news, the Company's share price fell $3.30, or 8.05%, to close at $37.69 per share on October 8, 2020, on unusually heavy trading volume.

15. Other publications were likewise shocked at the Company's failure to disclose the material information about the safety signal and likewise linked the FDA's investigation to the NISS with the CRL rejecting the NASH NDA. For example, an October 13, 2020 article noted that:

> Intercept last week added to its woes after a sharp-eyed investor noticed that modified boilerplate language in the company's quarterly filing implied further toxicity problems for Ocaliva. ***The revelation, missed by all the sellside, knocked 8% off the company's already battered stock price last week.***
>
> ***
>
> In last week's 10-Q filing Intercept slipped out the fact that the FDA had "begun to evaluate a newly identified safety signal regarding liver disease for Ocaliva ... as a potential risk". ***Remarkably, this review had begun in May, but had not been mentioned publicly until now.***
>
> ***Whatever the reason for Intercept not mentioning the FDA review until last week, the fact that this started in May fits chronologically with the Nash adcom postponement. Investors will now want to know whether the new toxicity signals were behind the June CRL, and whether they presage further restrictions on Ocaliva's approved PBC indication; the label already has a black boxed warning.***

16. Defendants acted with scienter and must be held accountable for their wrongful acts and omissions which, as the true facts came to light, were the cause of a significant decline in the market value of the Company's securities. Plaintiffs and other Class members have suffered significant losses and damages at the hands of Defendants and are entitled to redress.

II. JURISDICTION AND VENUE

17. The claims asserted herein arise under Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. § 240.10b-5).

18. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and Section 27 of the Exchange Act (15 U.S.C. § 78aa).

19. Venue is proper in this Judicial District pursuant to 28 U.S.C. § 1391(b) and Section 27 of the Exchange Act (15 U.S.C. § 78aa(c)). Substantial acts in furtherance of the alleged fraud or the effects of the fraud have occurred in this Judicial District. Many of the acts charged herein, including the dissemination of materially false and/or misleading information, occurred in substantial part in this Judicial District. Additionally, the Company's principal executive offices are located in this Judicial District.

20. In connection with the acts, transactions, and conduct alleged herein, Defendants directly and indirectly used the means and instrumentalities of interstate commerce, including the United States mail, interstate telephone communications, and the facilities of a national securities exchange.

III. PARTIES

A. Plaintiffs

21. Lead Plaintiff, as set forth in the certification previously filed with the Court, purchased Intercept securities during the Class Period and suffered damages as a result of the federal securities law violations and false and/or misleading statements and/or material omissions alleged herein.

22. Plaintiff Christian Stankevitz, as set forth in the certification attached hereto, purchased Intercept securities during the Class Period and suffered damages as a result of the federal securities law violations and false and/or misleading statements and/or material omissions alleged herein.

B. Defendants

23. Defendant Intercept is incorporated under the laws of Delaware and its principal executive offices are located at 10 Hudson Yards, 37th Floor, New York, NY 10001. Intercept's common stock trades on the Nasdaq exchange under the symbol "ICPT."

24. Defendant Mark Pruzanski, M.D. ("Pruzanski") is one of the Company's co-founders and served as the Company's President and Chief Executive Officer from the Company's inception in 2002 until January 1, 2021. Additionally, Pruzanski has been a director of the Company's Board at all relevant times. According to the Company, Pruzanski has over 20 years of experience in life sciences company management, venture capital and strategic consulting. Prior to co-founding the Company, he was a venture partner at Apple Tree Partners, an early stage life sciences venture capital firm that he co-founded, and an entrepreneur-in-residence at Oak Investment Partners, a venture capital firm. Pruzanski received his M.D. from McMaster University in Hamilton, Canada, a M.A. degree in International Affairs from the Johns Hopkins University School of Advanced International Studies in Bologna, Italy and Washington, D.C., and a bachelor's degree from McGill University in Montreal, Canada.

25. Defendant Sandip Kapadia ("Kapadia") was the Company's Chief Financial Officer and Treasurer from July 2016 until March 26, 2021. According to the Company, Kapadia has over 20 years of experience in building and leading finance and administration teams at life sciences companies both in the United States and abroad. Prior to joining the Company, Kapadia held finance leadership positions over 19 years at Novartis and Novartis affiliates in the United States, Switzerland, the Netherlands and the United Kingdom, including most recently Chief Financial Officer of North America at Novartis's generic division, Sandoz. Kapadia has been a director of Passage Bio since January 2020 and previously was a director of Therachon AG from January 2019 to June 2019. Kapadia earned his bachelor's degree in business administration and accounting from Montclair State University and an M.B.A from Rutgers Graduate School of Management. He is a certified public accountant.

26. Defendants Pruzanski and Kapadia are also referred to hereinafter as the "Individual Defendants." The Individual Defendants, because of their positions with the Company, possessed the power and authority to control the contents of the Company's reports to the SEC, press releases and presentations to securities analysts, money and portfolio managers and institutional investors, *i.e.*, the market. The Individual Defendants were provided with copies of the Company's reports and press releases alleged herein to be misleading prior to, or shortly after, their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. Because of their positions and access to material non-public information available to them, the Individual Defendants knew that the adverse facts specified herein had not been disclosed to, and were being concealed from, the public, and that the positive representations which were being made were then materially false and/or misleading. The Individual Defendants are liable for the false statements pleaded herein.

IV. STATEMENT OF FACTS

27. Intercept is a biopharmaceutical company focused on the development and commercialization of novel therapeutics to treat progressive non-viral liver diseases, including primary biliary cholangitis ("PBC") and nonalcoholic steatohepatitis ("NASH"). The Company was founded in 2002 in New York and currently has operations in the United States, Europe and Canada. Its sole drug candidate is obeticholic acid or "OCA."

A. Liver Function And Bile Acid

28. The liver performs many vital functions, including the regulation of bile acids, which are natural detergent-like emulsifying agents that are released from the gallbladder into the intestine when food is ingested to aid the absorption of dietary cholesterol and other nutrients. The biological effects of bile acids are mediated through dedicated receptors.

29. According to the Company, the best understood receptor is FXR, a nuclear receptor that regulates bile acid synthesis and clearance from the liver, thereby preventing excessive bile acid build-up in the liver, which may be toxic. Therefore, FXR is a target for the treatment of several liver diseases that involve impaired bile flow, a condition called cholestasis.

In cholestasis, the liver is typically exposed to higher-than-normal levels of bile acids, which can cause significant damage over time. Additionally, according to the Company, bile acid activation of FXR is believed to induce anti-fibrotic, anti-inflammatory, anti-steatotic and other mechanisms that are necessary for the normal regeneration of the liver. As a result, FXR is also a target for the treatment of more common liver diseases such as NASH and alcoholic hepatitis.

B. Intercept Brings OCA To Market For PBC

30. PBC is a common liver disease that leads to the progressive destruction of the ducts that transport bile from the liver to the small intestine to digest fat and fat-soluble vitamins. When the ducts are destroyed, bile builds up in the liver contributing to inflammation and scarring (fibrosis). Eventually this can lead to cirrhosis and its associated complications, as scar tissue replaces healthy liver tissue and liver function becomes increasingly impaired.

1. Ocaliva's Approval For PBC

31. According to the Company, OCA is a bile acid analog, a chemical substance that has a structure based on a naturally occurring human bile acid, that selectively binds to and activates FXR, which may effectively counter a variety of chronic insults to the liver that cause fibrosis (scarring), that can eventually lead to cirrhosis, liver transplant and death. Due to OCA's bile acid-like properties, it circulates enterohepatically and engages FXR in both the liver and intestine. FXR engagement in the liver is believed to be critical to successfully treat pathologic injury due to progressive underlying disease.

32. In May 2016, using clinical trial data, Intercept obtained FDA approval through an accelerated approval pathway to market OCA for the treatment of PBC in combination with ursodeoxycholic acid ("UDCA")[3] in adults with an inadequate response to UDCA or as

[3] Prior to Ocaliva, the only approved drug for the treatment of PBC was ursodeoxycholic acid, available generically as ursodiol, which is widely considered the standard first line therapy for PBC patients. In patients for whom ursodiol is effective, the treatment slows the progression of PBC, reducing the likelihood of liver failure and the need for transplant.

monotherapy in adults unable to tolerate UDCA. [4] The Company has commercialized OCA under the brand name Ocaliva®. Since then, it has also been approved in the European Union and several other jurisdictions, including Canada, Israel and Australia. Moreover, Ocaliva received orphan drug designation in both the United States and the European Union for the treatment of PBC.[5]

33. Following approval, Intercept initiated the Phase 4 COBALT confirmatory outcomes trial as part of the post-marketing regulatory requirements to confirm that Ocaliva is associated with a longer-term benefit on liver-related clinical outcomes.

2. Misdosing Of Ocaliva Results In Deaths And Label Changes

34. According to the Company, in the course of its post-marketing pharmacovigilance[6] activities, deaths had been reported in PBC patients with moderate or severe hepatic impairment. Intercept performed an analysis, in consultation with the FDA, and concluded that certain of these patients were prescribed once daily doses of Ocaliva, which is seven times higher than the recommended weekly dose in such patients. As a result, in September 2017, Intercept issued a Dear Health Care Provider letter.

35. In February 2018, the Ocaliva label in the United States was updated by the FDA to include a boxed warning, commonly referred to as a "black box warning," and a dosing table that reinforced the then-existing dosing schedule for patients with Child-Pugh Class B or C or

[4] However, as OCA's prescribing information explains, the study also showed that when 25 mg and 50 mg of the drug were used per day that there was a corresponding increase in adverse events. https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/207999s000lbl.pdf

[5] Orphan drug designation awards market exclusivity for seven years as well as other financial incentives.

[6] "Pharmacovigilance" is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug related problem. It aims to enhance patient care and patient safety and to support public health programs by providing reliable, balanced information for the effective assessment of the benefit-risk profile of medicines and vaccines.

decompensated cirrhosis. In addition, the FDA issued an updated drug safety communication to accompany the revised label.

3. Intercept Successfully Brings Ocaliva To Market

36. The roll-out of Ocaliva for PBC was a success and sales have continued to increase since the launch. By the first fiscal quarter of 2017, Intercept had approximately $21 million in sales from the drug. The next fiscal year, 2018, the Company had $35 million in sales in the same quarter, and then $52 million in sales in the same quarter of fiscal 2019. Finally, in the 2020 fiscal first quarter, the Company had $73 million in Ocaliva sales.

C. The Company Seeks To Demonstrate OCA Can Treat NASH

37. While the Company believed that there were approximately 290,000 people worldwide with PBC at the time of Ocaliva's launch, there were other liver diseases that affected broader populations. For example, according to the Company, it is estimated that between 3% and 5% of the world's population has NASH. Intercept made a strategic decision to pursue the massive NASH market for which no medications had yet been approved.

38. NASH is a progressive liver disease caused by excessive fat accumulation in the liver (steatosis) that induces chronic inflammation, resulting in progressive fibrosis (scarring) that can lead to cirrhosis, eventual liver failure, cancer and death. According to the Company, more than 20% of patients with NASH are estimated to progress to cirrhosis within a decade of diagnosis and, compared to the general population, have a ten-fold greater risk of liver-related mortality.

39. In September 2015, the Company announced the initiation of its Phase 3 REGENERATE trial of OCA in patients with liver fibrosis due to NASH.[7] According to the Company, the goal of the REGENERATE study was to evaluate the safety and efficacy of OCA,

[7] In late July 2014, OCA achieved the primary endpoint in a Phase 2b clinical trial called FLINT for the treatment of NASH.

the same drug that was approved for treading PBC, in adult patients with NASH and liver scarring (fibrosis) without cirrhosis.[8] As the study itself explained:[9]

> **Primary Outcome Measures:**
>
> **1) To evaluate the effect of Obeticholic Acid compared to placebo on liver histology in non-cirrhotic nonalcoholic steatohepatitis (NASH) subjects with stage 2 or 3 fibrosis by assessing the following primary endpoints [Time Frame: Measurements at Baseline and 18 months]**
>
> Primary endpoints include:
>
> - The proportion of Obeticholic Acid treated patients relative to placebo achieving at least one stage of liver fibrosis improvement with no worsening of NASH, or
> - The proportion of Obeticholic Acid treated patients relative to placebo achieving NASH resolution with no worsening of liver fibrosis.
>
> 2) To evaluate the effect of Obeticholic Acid compared to placebo on all-cause mortality and liver-related clinical outcomes as measured by the time to first occurrence of any of the listed adjudicated events (clinical outcomes composite endpoint) [Time Frame: Time to accrue a pre-specified number of adjudicated events, End of Study, estimated to be 7 years]
>
> Primary endpoint events include:
>
> - Death (all cause), model of end stage liver disease (MELD) score ≥15, liver transplant, ascites requiring medical intervention, histological progression to cirrhosis, hospitalization (as defined by a stay of ≥24 hours) for onset of: variceal bleed, hepatic encephalopathy, spontaneous bacterial peritonitis.

40. The REGENERATE study was a randomized, double-blind, placebo-controlled, multicenter study assessing the safety and efficacy of OCA on liver-related clinical outcomes in patients with liver fibrosis due to NASH. Patients with biopsy-proven NASH with fibrosis were randomized 1:1:1 to receive placebo, OCA 10 mg or OCA 25 mg once daily.[10]

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[8] According to the Company, fibrosis is the most robust predictor of long-term overall mortality, liver transplantation, and liver-related events in patients with NASH, and more than 30% of those patients are believed to have fibrosis of stage 2 or greater. As such, the trial sought improvement in fibrosis as indicative of patient improvement.

[9] https://clinicaltrials.gov/ct2/show/NCT02548351.

[10] In August 2019, the Company announced the completion of the enrollment of the clinical outcomes cohort of REGENERATE, with 2,480 adult NASH patients with fibrosis randomized at over 300 qualified centers worldwide.

D. Defendants Become Aware That OCA Is Causing Serious Adverse Events Yet Fail To Disclose The Adverse Events And That The FDA Had Identified Them As A Safety Signal In Need Of Further Investigation

41. Defendants continued to monitor the effects of OCA on their PBC patients as part of their pharmacovigilance responsibilities and their post-marketing regulatory requirements. As Defendant Pruzanski explained in February 2018, "With respect to future engagement with FDA, we'll continue our routine pharmacovigilance in the postmarketing setting and continue to report and adjudicate cases as they come in to FDA and continue engaging with them."

42. It is clear that as part of these processes Defendants became aware of several active liver toxicity signals that were not already cited on Ocaliva's label. Such non-labeled events (*i.e.* risks that were not previously addressed or not known about and previously addressed by the FDA) could result in further restrictions on Ocaliva's use and thus the market size for the drug.

43. For example, an analysis of the FDA's FAERS[11] adverse event reporting system details which liver toxicity signals were not cited on the drug's label:[12]

[11] The FDA Adverse Event Reporting System ("FAERS") is a database that contains information on adverse event and medication error reports submitted to FDA.

[12] *See* https://www.evaluate.com/vantage/articles/news/policy-and-regulation/shedding-light-intercepts-opaque-disclosure

Most frequently reported adverse events for Ocaliva in the hepatobiliary system organ class				
Adverse event	**US label status**	**Cases (primary)**	**ROR***	**Event type**
Chronic hepatic failure	Not labelled	6	18.21	Serious
Bile duct stenosis	Labelled	7	11.56	Serious
Portal hypertension	Not labelled	12	8.87	Serious
Cholangitis acute	Labelled	3	6.26	Serious
Hepatic cirrhosis	Labelled	33	5.62	Serious
Hepatic failure	Not labelled	61	5.47	Serious
Hepatic fibrosis	Labelled	9	5.35	Serious
Bile duct stone	Labelled	8	5.12	Serious
Hepatorenal syndrome	Not labelled	6	5.08	Serious
Hyperbilirubinaemia	Labelled	18	4.52	Serious
Autoimmune hepatitis	Not labelled	6	1.83	Serious
*Note: *risk odds ratio.* *Source: Advera Health Analytics.*				

44. These risks include chronic hepatic failure (chronic liver failure), portal hypertension, hepatic failure (liver failure) and hepatorenal syndrome from in-market use of Ocaliva for PBC. Clearly, liver failure and other life-threatening liver diseases are problematic side effects for a drug that is meant to improve liver function.

45. The "ROR" column in the chart refers to the "risk odds ratio." As the article[13] explains:

[13] *See* https://www.evaluate.com/vantage/articles/news/policy-and-regulation/shedding-light-intercepts-opaque-disclosure

> In terms of frequency of these events, the relevant metric is the risk odds ratio (ROR). An ROR score above 1 indicates a higher than expected reporting rate for a given adverse event, and while there is no widely accepted benchmark regarding the level triggering a safety signal many in the industry assume that results above 2.0 warrant attention . . . .

46. Whereas ROR scores above 2 warrant attention, scores of more than 18 and almost 9 for liver failure and portal hypertension, respectively, are staggering. As such, it is absurd to think that the Company would not have been aware of these adverse events, and the others, for its lone-approved drug that was responsible for all of Intercept's revenue.

47. In fact, the Company was aware of these adverse events. The FAERS system provides substantial information about each adverse event, including when the FDA first learned about the adverse event (Initial FDA Received Date).[14] From the FAERS system, it is clear that Intercept and its executives were learning about these adverse events in essentially real-time and were aware of these issues before the start of the Class Period, and certainly, by the time they were specifically informed of the NISS in May 2020. For example, with hepatorenal syndrome, all six events occurred before the start of the Class Period. Likewise, the FDA was informed of all adverse events of chronic hepatic failure by March 2020 (four of them had occurred before the start of the Class Period), seven of the portal hypertension events occurred before the Class Period, and the four other events prior to the NISS occurred by February 2020.

48. While the Company chose not to disclose these known adverse events to the market, the FDA ultimately informed Defendants in May 2020 that it had identified a Newly Identified Safety Signal ("NISS") with Ocaliva related to liver disorder. As the Company explained after the Class Period:

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[14] While it is unclear exactly when the Company would have learned about these serious adverse events, the only reasonable inference is that the Company and its Safety & Pharmacovigilance department (led by Gail Cawkwell, Senior Vice President, Medical Affairs, Safety & Pharmacovigilance Operating Officer) was learning of them near real-time through the monitoring of the FAERS system as well as maintaining its own internal safety database as part of its post-marketing regulatory requirements and through its continuous communications with the FDA.

> The FDA has notified us that, in the course of its routine safety surveillance, in May 2020 the FDA began to evaluate a newly identified safety signal, or NISS, regarding liver disorder for Ocaliva which the FDA classified as a potential risk. The FDA has informed us that its review of the NISS is focused on a subset of the cirrhotic, or more advanced, PBC patients who have taken Ocaliva.

49. The Company did not disclose this information following this notification from the FDA even though it could impact both the labeling and market for Ocaliva for PBC treatment and the NASH NDA. Instead, Defendants attempted to bury the information from the market and only released any real information about it after they were caught attempting to hide the news.

E. Intercept Goes Forward With Their NASH NDA Submission Yet Misleads The Public By Failing To Disclose That There Are New Safety Issues With The Same Drug

50. Intercept sought to have OCA, the same drug that had previously been approved for PBC treatment, approved for treatment in NASH. As such, any information related to the long-term safety of OCA in PBC would certainly be of interest to the FDA and other regulatory organizations that were attempting to determine if the drug's safety and efficacy warranted approval for use with NASH patients.

51. In fact, the adverse events found within the PBC population were especially relevant because they depicted the impact of long-term use of OCA (potentially longer than 18 months, even multiple years), whereas the clinical results supporting NASH were based on a short-term study of 18 months. Moreover, a PBC study had already determined that 25 mg per day of OCA (*i.e.*, the same dosage Intercept sought to have approved to treat NASH) led to a proportional increase in serious adverse events.

1. Intercept Uses Positive Topline Results In Its NASH Study To Raise $450 Million

52. In February 2019, the Company announced topline results from the planned 18-month interim for the Phase 3 clinical trial of OCA in patients with liver fibrosis due to NASH – the REGENERATE trial. According to the Company, in the primary efficacy analysis, once-daily OCA 25 mg met the primary endpoint agreed with the FDA (*i.e.*, fibrosis improvement by at least one stage with no worsening of NASH at the planned 18-month interim analysis). As to

safety, adverse events were generally mild to moderate in severity, and the most common were consistent with the known profile of OCA.

53. With these promising results, the Company was able to raise approximately $450 million in May 2019 through a sale of convertible notes, the issuance and sale of common stock in a public offering, and a concurrent private placement of common stock.

2. The Company Announces And Proceeds With Its NASH NDA Submission But Fails To Disclose The Serious Adverse Events With OCA In PBC Patients

54. On September 27, 2019, the Company announced that it had submitted an NDA to the FDA for OCA in patients with fibrosis due to NASH. According to the Company:

> OCA is the only investigational therapy to meet the primary endpoint of a Phase 3 study in patients with NASH and is the only such therapy that the FDA has designated a Breakthrough Therapy for NASH with fibrosis. As such, Intercept has requested a Priority Review for the NDA, which, if granted, would result in an anticipated six-month review period.

Moreover, Intercept explained that the "submission is based on positive interim analysis results from the pivotal Phase 3 REGENERATE study in patients with liver fibrosis due to NASH." Specifically, it stated that "In the study, OCA 25 mg achieved its primary endpoint by demonstrating robust improvement in liver fibrosis (by ≥1 stage) without worsening of NASH at 18 months (p=0.0002 vs placebo)."

55. Nowhere in this announcement did the Company or its executives disclose or mention that serious liver-related adverse events associated with the same drug posed serious risks to approval of the NDA. This is particularly surprising because, as the Company admitted in its quarterly and annual reports both before and during the Class Period, "any safety concerns associated with Ocaliva, ***perceived or real***, may adversely affect the successful development and commercialization of our product candidates and lead to a loss of revenues."

56. On November 25, 2019, the Company disclosed that the FDA had accepted Intercept's NDA for OCA seeking accelerated approval for the treatment of fibrosis due to NASH and had granted priority review. As the Company explained, the FDA grants priority review to drugs that have the potential to treat a serious condition and, if approved, would

provide a significant improvement in safety or effectiveness. Moreover, the Company disclosed that the FDA assigned Prescription Drug User Fee Act ("PDUFA") target action date of March 26, 2020 for the NDA.[15] In the NDA filing acceptance notification letter, the FDA also indicated that it currently plans to hold an advisory committee meeting ("AdCom") to discuss the application.

57. On December 13, 2019, the Company announced that the FDA had tentatively scheduled the AdCom for April 22, 2020. Intercept anticipated that the FDA accordingly would extend the recently announced March 26, 2020 PDUFA target action date for Intercept's NDA.

58. On January 17, 2020, the Company announced that the FDA has officially extended its PDUFA date for its NASH NDA to June 26, 2020, *i.e.*, an extension of three months.

59. On March 26, 2020, the Company disclosed that the AdCom, which had previously been tentatively scheduled for April 22, 2020, had been postponed and was now tentatively scheduled for June 9, 2020. The Company further explained that it continued to work closely with the FDA on its priority review application and that the PDUFA target action date remains June 26, 2020.

60. Throughout this entire period, the Company and its executives repeatedly discussed that they were diligently preparing for the AdCom, including reviewing relevant safety information. For example, on the Company's November 5, 2019 conference call, Defendant Pruzanski explained that:

> With respect to your question about ADCOM. I mentioned earlier that we're preparing for one, if there is one, if FDA decides to have one. And I think in terms of the focus of interest at that ADCOM, it would ultimately go to -- across the board to efficacy and safety and overall benefit/risk.

[15] PDUFA dates are deadlines for the FDA to review new drugs. The FDA is normally given 10 months to review new drugs, but if a drug is selected for priority review, the FDA is allotted 6 months for review. These time frames begin on the date that an NDA is accepted by the FDA.

61. Likewise, on the Company's February 25, 2020 conference call, Defendant Pruzanksi further emphasized that:

> Planning for an AdCom is a major undertaking, and we are confident that we will be well prepared. We have the prior experience of our successful AdCom preceding our PBC approval, and our team has been doing an excellent job to prepare for the one upcoming.
>
> Engaging with a wide range of external experts, we continue to be confident that we will be able to effectively demonstrate OCA's strong value proposition for patients and positive benefit risk. As I often say, we did not take any shortcuts in our extensive development program and have assembled a great amount of data supporting our breakthrough-designated drug safety and efficacy profile in NASH fibrosis.

62. The only logical inference is that such an exhaustive and massive undertaking into preparing for the AdCom, which would focus on the safety and benefit of OCA for NASH, would uncover the recent, serious liver-related adverse events from the same drug impacting the same organ (the liver).

3. Even After The FDA Informs The Company About The NISS, Intercept Still Fails To Disclose The Truth

63. As the Company later admitted, in May 2020, the FDA specifically informed Defendants that it had begun to evaluate a NISS regarding liver disorder for Ocaliva, which the FDA classified as a potential risk. The Company further admitted after the Class Period that the review of the NISS was focused on a subset of the cirrhotic, or more advanced, PBC patients who have taken Ocaliva.

64. Defendants did not promptly disclose this fact that could lead to a potential revision to the labeling of Ocaliva for PBC and thus could greatly impact the potential market and sales for the drug. Moreover, Defendants also did not disclose this information, which was a material risk to the pending NASH NDA.

65. Soon thereafter, the Company disclosed on May 22, 2020 that the FDA had notified Defendants that it was postponing the AdCom to allow for the review of additional data the agency had requested. Defendant Pruzanski represented, however, that the Company was engaged in a dialogue with the FDA and that "we believe that the additional data being submitted

will be important in facilitating a more informed discussion at the AdCom" and "We remain confident in our NDA submission."

66. Nowhere in this disclosure, or any related disclosure by Defendants, was the NISS disclosed.

67. On June 29, 2020, the Company disclosed that announced that the FDA had issued a Complete Response Letter ("CRL") regarding the NASH NDA that "indicated that, based on the data the FDA has reviewed to date, the [FDA] has determined that the predicted benefit of OCA based on a surrogate histopathologic endpoint remains uncertain and does not sufficiently outweigh the potential risks to support accelerated approval for the treatment of patients with liver fibrosis due to NASH." Again, even though the FDA had specifically stated that a reason for the CRL was that the drug's "potential risks" were not outweighed by the drug's benefit, Defendants failed to disclose the safety signal regarding the same drug that the FDA was investigating in this disclosure or the Company's corresponding investor calls/conferences.

4. The Company Attempts To Hide The NISS, But Is Ultimately Forced To Reveal Its Existence

68. Even after the Company received its CRL for the NASH NDA, it still failed to disclose the NISS. This is possibly because executives did not want to further negatively impact the Company's stock price, which had been decimated from the CRL disclosure, or the Company's reputation and credibility in the marketplace. Regardless of the reason, prior to August 10, 2020, there was not a single mention of it by the Company or any of its executives or officers.

69. Faced with the reality that the Company had to eventually disclose the NISS and FDA investigation at some point, Defendants decided to attempt to bury the news. They did this by inserting language about the safety signal in middle of boilerplate paragraphs deep in the quarterly report (57 and 63) of the Company's August 10, 2020 quarterly report:

> In the course of our post-marketing pharmacovigilance activities, deaths have been reported in PBC patients with moderate or severe hepatic impairment. In an analysis performed by us and in consultation with the FDA, we concluded that certain of these patients were prescribed once daily doses of Ocaliva, which is seven times higher than the recommended weekly dose in such patients. As a

> result, in September 2017, we issued a DHCP letter and the FDA also subsequently issued its own drug safety communication to reinforce recommended label dosing. Both communications remind healthcare providers of the importance of the recommended reduced dosing of Ocaliva in PBC patients with moderate or severe hepatic impairment, while reiterating the importance of monitoring PBC patients for progression of their disease and the occurrence of liver-related adverse reactions. In February 2018, we announced that the Ocaliva label in the United States had been updated by the FDA to include a boxed warning and a dosing table that reinforced the then-existing dosing schedule for patients with Child-Pugh Class B or C or decompensated cirrhosis. In addition, the FDA issued an updated drug safety communication to accompany the revised label. We remain focused on the safety of all of the patients using Ocaliva within and outside of our ongoing clinical studies and have engaged with relevant regulatory authorities to ensure that the Ocaliva label sufficiently reinforces the importance of appropriate dosing in patients with advanced cirrhosis. The FDA has notified us that in the course of its routine safety surveillance, in May 2020 the FDA began to evaluate a newly identified safety signal regarding liver disorder for Ocaliva which the FDA classified as a potential risk. Pursuant to FDA guidance, this does not mean that the FDA has concluded that the drug has the listed risk or that the FDA has identified a causal relationship between Ocaliva and the potential risk. As part of our routine pharmacovigilance efforts, we have worked with the FDA to reconcile our internal safety database with the FDA Adverse Event Reporting System database and have been conducting additional signaling analysis and monitoring activities. Any safety concerns associated with Ocaliva, perceived or real, or future label changes required by the FDA or other relevant regulatory authorities may materially and adversely affect our Ocaliva commercialization efforts and, consequently, our financial condition and results of operations.

70. The NISS was not addressed in either the Company's press release announcing its quarterly results or the corresponding earnings call. In fact, it appeared that the burying was successful because no one, including analysts, noticed the comment.

71. It was not until months later that someone noticed the change in the Company's boilerplate disclosures (where the language had been included) and tweeted about it. Even then it took an article published by Stat+, entitled "FDA investing whether Intercept Pharma drug is tied to potential liver injury risk"[16] for the market realize that the FDA was investigating the NISS. As the article explained:

> The Food and Drug Administration is evaluating a potential risk of liver injury in patients who take the Intercept Pharmaceuticals drug Ocaliva to treat a certain type of liver disease.

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[16] Available at https://www.statnews.com/2020/10/08/fda-investigating-whether-intercept-pharma-drug-is-tied-to-potential-liver-injury-risk/.

> The FDA's inquiry into Ocaliva began in May and could take one year to complete, Intercept spokesperson Christopher Frates told STAT. Intercept is cooperating with the FDA's safety regulators, and "based on our work to date, we remain confident in the positive benefit-risk profile of Ocaliva when used as directed," Frates said.
>
> ***Intercept has not previously said anything publicly about the FDA examination. Instead, the company chose to disclose the inquiry by adding several new sentences to an existing risk-statement paragraph on the 57th page of its most recent quarterly report filed with the Securities and Exchange Commission.*** The change was picked up by a health care investor on Twitter earlier this week.
>
> In the same SEC filing, ***Intercept warned any safety concern associated with Ocaliva, "perceived or real," could negatively impact the drug's sales or its effort to expand use into other types of liver disease.***
>
> ***
>
> ***Did the FDA's liver safety evaluation of Ocaliva, which began in May, contribute to the agency's decision in June to reject the NASH application?***
>
> "The NISS was not raised in the context of the review of our NASH [application] and we have no reason to believe that it was associated with the FDA's decision to issue the complete response letter," Frates told STAT. NISS refers to "newly identified safety signal," which is the FDA's technical term for a safety evaluation of an already-approved drug.

72. Other publications were likewise shocked at the Company's failure to disclose this material information and likewise linked the FDA's investigation to the NISS with the CRL rejecting the NASH NDA. For example, an October 13, 2020 article entitled "Shedding light on Intercept's opaque disclosure," stated:

> Intercept last week added to its woes after a sharp-eyed investor noticed that modified boilerplate language in the company's quarterly filing implied further toxicity problems for Ocaliva. ***The revelation, missed by all the sellside, knocked 8% off the company's already battered stock price last week.***
>
> Without further information about the precise toxicities that the US FDA has apparently been looking into since May it is impossible to quantify the possible problem, but the safety database Advera Health Analytics sheds important light on the matter. Meanwhile, during a major biotech boom, Intercept stands off 68% on the year.
>
> The group's big knockback, of course, occurred in June when the FDA handed Ocaliva a complete response letter for Nash, apparently citing concerns that activity based on a surrogate histopathologic endpoint might not outweigh potential risks (The dream is over for Intercept, June 29, 2020).
>
> ***

> In last week's 10-Q filing Intercept slipped out the fact that the FDA had "begun to evaluate a newly identified safety signal regarding liver disease for Ocaliva ... as a potential risk". ***Remarkably, this review had begun in May, but had not been mentioned publicly until now.***
>
> ***Whatever the reason for Intercept not mentioning the FDA review until last week, the fact that this started in May fits chronologically with the Nash adcom postponement. Investors will now want to know whether the new toxicity signals were behind the June CRL, and whether they presage further restrictions on Ocaliva's approved PBC indication; the label already has a black boxed warning.***
>
> But the bigger opportunity in Nash is most at risk. For now the sellside remains incredibly bullish, with 2026 consensus at $2bn, according to Evaluate Pharma, even with mounting evidence that this drug is not going anywhere fast.

5. The NISS Leads To A Labeling Change For Ocaliva While The Company's Long-Term CEO And Chief Medical Officer Leave Intercept

73. On November 9, 2020, the Company finally addressed the NISS during one of its earnings calls with investors and analysts. Therein, Defendant Pruzanski disclosed that it would be a "12-month timeline for the evaluation of this kind of NISS." Moreover, he further explained "that this potential Ocaliva risk in PBC was identified in the course of FDA's routine safety monitoring activities based on a search of the FAERS database and other available external sources," meaning the Company also had access to the same information in addition to its internal databases.

74. Thereafter, at the Piper Sandler 32nd Annual Healthcare Conference on December 1, 2020, the Company's Senior Vice President of Medical Affairs, Safety & Pharmacovigilance, Gail Cawkwell, again admitted that the FDA had notified them of the liver disorder signal in May and that the Company was in an ongoing dialogue with them regarding the signal. And she explained: "In this case, FDA contacted us earlier this year, in May of this year, and they had identified a signal, which they qualified as a signal of liver disorder, kind of a broad category and we followed up with them to get more detail…."

75. On December 10, 2020, the Company announced that Defendant Pruzanski would leave his post as CEO of Intercept after 19 years in the role, effective January 1, 2021.

76. Thereafter, Jason Campagna, the Company's Chief Medical Officer who had previously been the NASH Program Leader at Intercept for several years, tendered his resignation on February 18, 2021. According to the Company, he was leaving for other opportunities, but news reports indicated this was not the case. For example, an article in Endpoints News explained that:

> analysts suggested his departure could be part of a broader shift as the company continues to game out its future, after the FDA rejected their long-watched NASH drug last June.
>
> Campagna led the company's NASH program after he was hired from The Medicines Company in 2016. ***His departure***, along with the decision to replace Pruzanski with a CEO whose expertise is on commercializing, rather than developing, drugs ***could signal that Intercept thinks it will be difficult to collect the NASH data the FDA wants*** and is instead deciding to focus on its already approved PBC program.[17]

77. On February 25, 2021, the Company's new CEO, Jerry Durso explained that the Company had met with the FDA regarding the NISS for liver disorder and that the FDA had indicated "that the process will ultimately result in a change to our label regarding the use of Ocaliva to treat patients who reach the most advanced stages of PBC." Moreover, the Company's Annual Report issued that same day further disclosed that the "FDA has informed us that its review of the NISS is focused on a subset of the cirrhotic, or more advanced, PBC patients who have taken Ocaliva" and "We are working with the FDA to align on changes to the Ocaliva label regarding patients with the most advanced stages of PBC. Based on our communications with the FDA, this update will come in the form of a safety labeling change."

78. On this news, the Company's stock declined by more than 21%.[18]

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[17] Available at https://endpts.com/intercept-shakeup-continues-as-cmo-former-nash-chief-resigns-is-the-nash-biotech-abandoning-its-flagship-disease/.

[18] The next day, the Company's executives confirmed that the anticipated labeling change would negatively impact the sales of Ocaliva going forward.

V. MATERIALLY FALSE AND MISLEADING STATEMENTS AND OMISSIONS MADE WITH SCIENTER DURING THE CLASS PERIOD

79. Throughout the Class Period, Defendants were aware or were reckless in not knowing that there were serious adverse events with Ocaliva in PBC patients that created a material risk to the Company's NASH NDA, where the FDA was considering the safety and efficacy of a higher dose of the same drug. Moreover, Defendants were aware or reckless in not knowing that these safety issues, as well as the FDA's investigation of these same issues, created a substantial, undisclosed risk to Intercept's future revenue from Ocaliva sales to PBC patients and business. Yet, they failed to disclose the true condition of the Company to the public during the Class Period.

A. Defendants' False And Misleading Statements Disseminated To The Public On September 27, 2019

80. On September 27, 2019, Intercept issued a press release entitled "Intercept Submits New Drug Application to the U.S. FDA for Obeticholic Acid in Patients with Fibrosis Due to NASH." Therein, the Company stated, in relevant part:

> Intercept Pharmaceuticals, Inc. (Nasdaql1CPT), a biopharmaceutical company focused on the development and commercialization of novel therapeutics to treat progressive non-viral liver diseases, today announced that it has submitted a New Drug Application (NDA) to the U.S. Food and Drug Adminstration (FDA) for obeticholic acid (OCA) for the treatment of patients with fibrosis due to nonalcoholic steatohepatitis (NASH).
>
> OCA is the only investigational therapy to meet the primary endpoint of a Phase 3 study in patients with NASH and is the only such therapy that the FDA has designated a Breakthrough Therapy for NASH with fibrosis. As such, Intercept has requested a Priority Review for the NDA, which, if granted, would result in an anticipated six-month review period.
>
> The submission is based on positive interim analysis results from the pivotal Phase 3 REGENERATE study in patients with liver fibrosis due to NASH. In the study, OCA 25 mg achieved its primary endpoint by demonstrating robust improvement in liver fibrosis (by M stage) without worsening of NASH at 18 months (p=0.0002 vs placebo).
>
> "***Our submission of the first NDA for the treatment of fibrosis due to NASH is a very important milestone for the field and the culmination of more than a decade of hard work***," said Mark Pruzanski, M.D., President and Chief Executive Officer of Intercept. "I am grateful to the thousands of NASH patients participating in our clinical studies, the investigators and study personnel at our study sites around the globe, and the entire Intercept team for bringing us to this point. We look forward to continuing to work with the FDA through the NDA

> review period and believe that, if approved, OCA has the potential to become an essential treatment for people living with advanced fibrosis due to NASH."
>
> Intercept also intends to file a marketing authorization application (MAA) with the European Medicines Agency in the fourth quarter of this year.

81. The statements in ¶80 were materially false and/or misleading when made and/or omitted to state material facts necessary to make the statements not misleading, because they failed to disclose that there were several serious adverse events from OCA in PBC patients that were not already cited on Ocaliva's label and that these serious adverse events in patients taking the same drug was a material risk to approval of the NASH NDA.

B. Defendants' False And Misleading Statements Disseminated To The Public On November 5, 2019

82. On November 5, 2019, Intercept issued a press release entitled "Intercept Pharmaceuticals Reports Third Quarter 2019 Financial Results and Provides Business Update." Therein, the Company stated, in relevant part:

> "***During the third quarter, we submitted our NDA seeking accelerated approval of OCA for NASH in the U.S., a historic achievement for our company and a critically important milestone for the many patients currently without an approved treatment***," said Mark Pruzanski, M.D., President and Chief Executive Officer of Intercept. "With the submission behind us, we are actively preparing to launch the first therapy for advanced fibrosis due to NASH and our pre-launch disease state educational activities are accelerating with the continued expansion of our sales, medical and market access teams. In addition, we are looking forward to the presentation of important new data from the interim analysis of our ongoing Phase 3 REGENERATE study at the upcoming AASLD Liver Meeting. Based on our team's strong commercial execution in the third quarter, I am also pleased to announce that we are increasing our 2019 net sales guidance for Ocaliva to between $245 million and $250 million."

83. Additionally, during a conference call with analysts held also on November 5, 2019, Pruzanski stated, in relevant part:

> Let me begin my summary of the quarter by noting the achievement of a historic milestone with our submission of the first new drug application for NASH to the FDA.
>
> ***
>
> As we've previously stated, we are flexing up our existing infrastructure and capabilities while building on our relationships within the community in preparation for our NASH launch. Following its anticipated approval, OCA is positioned to become the foundational therapy in patients with advanced fibrosis due to NASH.

84. Moreover, during the same earnings call, defendant Pruzanski replied to a question about how the Company was preparing for the AdCom:

> Yes. With respect to your question about ADCOM. I mentioned earlier that we're preparing for one, if there is one, if FDA decides to have one. And I think in terms of the focus of interest at that ADCOM, it would ultimately go to -- across the board to efficacy and safety and overall benefit/risk. Needless to say, we're obviously very confident, based on all the data that we've seen, in the favorable benefit-risk profile of OCA at the 25-milligram dose, the effective dose in this population with advanced fibrosis.

85. Also on November 25, 2019, the Company filed its quarterly report on Form 10-Q for the period ended September 30, 2019 (the "3Q19 10-Q"). Therein, Intercept stated, as to the safety of Ocaliva:

> In the course of our post-marketing pharmacovigilance activities, deaths have been reported in PBC patients with moderate or severe hepatic impairment. In an analysis performed by us and in consultation with the FDA, we concluded that certain of these patients were prescribed once daily doses of Ocaliva, which is seven times higher than the recommended weekly dose in such patients. . . . ***We remain focused on the safety of all of the patients using Ocaliva within and outside of our ongoing clinical studies*** and have engaged with relevant regulatory authorities to ensure that the Ocaliva label sufficiently reinforces the importance of appropriate dosing in patients with advanced cirrhosis. ***These events and any safety concerns associated with Ocaliva, perceived or real, may adversely affect the successful development and commercialization of our product candidates and lead to a loss of revenues.***

86. The 3Q19 10-Q similarly went on to state:

> We remain focused on the safety of all of the patients using Ocaliva within and outside of our ongoing clinical studies and have engaged with relevant regulatory authorities to ensure that the Ocaliva label sufficiently reinforces the importance of appropriate dosing in patients with advanced cirrhosis. These events, the revised label, any future label changes that may be required by the FDA or other relevant regulatory authorities and ***any safety concerns associated with Ocaliva, perceived or real, may materially and adversely affect our Ocaliva commercialization efforts and, consequently, our financial condition and results of operations.***

87. The 3Q19 10-Q further stated:

> Additional or unforeseen side effects relating to OCA or any of our other product candidates could arise either during clinical development or, if approved, after the approved product has been marketed. With the approval of Ocaliva for PBC in the United States, Europe and certain of our other target markets, OCA is currently used in an environment that is less rigorously controlled than in clinical studies. If new side effects are found, if known side effects are shown to be more severe than previously observed or if OCA is shown to have other unexpected characteristics, we may need to abandon our development of OCA for PBC, NASH and other

> potential indications. Furthermore, our commercial sales of Ocaliva for PBC may be materially and adversely affected.

88. The statements in ¶¶82-87 were materially false and/or misleading when made and/or omitted to state material facts necessary to make the statements not misleading, because they failed to disclose that there were several serious adverse events from OCA in PBC patients that were not already cited on Ocaliva's label and that these serious adverse events in patients taking the same drug was a material risk to approval of the NASH NDA.

C. Defendants' False And Misleading Statements Disseminated To The Public On November 25, 2019

89. On November 25, 2019, Intercept issued a press release entitled "FDA Accepts Intercept's NDA for OCA for the Treatment of Liver Fibrosis Due to NASH and Grants Priority Review." Therein, the Company stated, in relevant part:

> Intercept Pharmaceuticals, Inc. (Nasdaq: ICPT), a biopharmaceutical company focused on the development and commercialization of novel therapeutics to treat progressive non-viral liver diseases, today announced that the U.S. Food and Drug Administration (FDA) has accepted Intercept's New Drug Application (NDA) for obeticholic acid (OCA) seeking accelerated approval for the treatment of fibrosis due to nonalcoholic steatohepatitis (NASH) and granted priority review. The FDA grants priority review to drugs that have the potential to treat a serious condition and, if approved, would provide a significant improvement in safety or effectiveness.
>
> "If approved, OCA would be the first available therapy for patients with fibrosis due to NASH, a condition that is expected to become the leading cause of liver transplant in the U.S. as soon as 2020," said Mark Pruzanski, M.D., President and Chief Executive Officer of Intercept. "It is exciting to achieve this critical regulatory milestone that brings us one step closer to our goal of delivering the first approved therapeutic to those living with this devastating disease. From OCA's prior designation as a Breakthrough Therapy to the grant of priority review today, our work with FDA continues to set an important precedent for the field, and we look forward to working with the agency over the coming months as they review the first NDA in NASH."
>
> The FDA has assigned a Prescription Drug User Fee Act (PDUFA) target action date of March 26, 2020 for the NDA. In the NDA filing acceptance notification letter, the FDA also indicated that it currently plans to hold an advisory committee meeting to discuss the application. A date for the advisory committee meeting has not been finalized and the timeline for the review of the NDA by the FDA remains subject to change.
>
> OCA is the only investigational therapy to have received Breakthrough Therapy designation from the FDA for NASH with fibrosis. The NDA filing for OCA is supported by positive interim analysis results from the pivotal Phase 3 REGENERATE study in patients with liver fibrosis due to NASH. In the study,

> OCA 25 mg demonstrated robust improvement in liver fibrosis (by ≥1 stage) with no worsening of NASH at 18 months.

90. The statements in ¶89 were materially false and/or misleading when made and/or omitted to state material facts necessary to make the statements not misleading, because they failed to disclose that there were several serious adverse events from OCA in PBC patients that were not already cited on Ocaliva's label and that these serious adverse events in patients taking the same drug was a material risk to approval of the NASH NDA.

D. Defendants' False And Misleading Statements Disseminated To The Public On February 25, 2020

91. On February 25, 2020, Intercept issued a press release entitled "Intercept Pharmaceuticals Reports Fourth Quarter and Full Year 2019 Financial Results, Issues 2020 Operating Expense Guidance and Provides Business Update." Therein, the Company stated, in relevant part:

> "2019 was a pivotal year for Intercept given the positive results in our Phase 3 REGENERATE study in liver fibrosis due to NASH and our subsequent filing for approval in both the U.S. and Europe," said Mark Pruzanski, M.D., President and Chief Executive Officer of Intercept. "At the same time, our commercial team's outstanding execution helped us deliver net sales of approximately $250 million for Ocaliva in 2019 and they continue to reach more PBC patients globally. As we enter 2020, we are focused on successfully completing the U.S. regulatory process and ensuring full readiness to launch the first approved therapy for patients suffering from fibrosis due to NASH."

92. Additionally, during an earnings call with analysts held also on February 25, 2020, Pruzanski stated, in relevant part:

> Recapping the year, I have to begin with the first and, so far, only successful pivotal Phase III NASH readout…. Of course, our Phase III results set the stage for the submission of our NDA, now under priority review by the FDA, with anticipated approval and launch within the first half of this year.
>
> We also continued to deliver exceptional results in our PBC business, with a strong finish in 2019, recording $250 million in net sales, representing 40% growth over the prior year and at the top end of our guidance. With Ocaliva now approved in 36 countries, we continue to expand access globally for PBC patients in need. ***And it was gratifying to report 5-plus year treatment data demonstrating durable safety and efficacy in our completed Phase III open-label extension study, while exceeding 10,000 patient years of experience in the PBC population.***

***

> Engaging with a wide range of external experts, we continue to be confident that we will be able to effectively demonstrate OCA's strong value proposition for patients and positive benefit risk. As I often say, we did not take any shortcuts in our extensive development program and have assembled a great amount of data supporting our breakthrough-designated drug safety and efficacy profile in NASH fibrosis.

93. Also on February 25, 2020, Intercept filed its annual report on Form 10-K with the SEC for the period ended December 31, 2019 (the "2019 10-K"). Therein, the Company stated:

> In the course of our post-marketing pharmacovigilance activities, deaths have been reported in PBC patients with moderate or severe hepatic impairment. In an analysis performed by us and in consultation with the FDA, we concluded that certain of these patients were prescribed once daily doses of Ocaliva, which is seven times higher than the recommended weekly dose in such patients. . . . ***We remain focused on the safety of all of the patients using Ocaliva within and outside of our ongoing clinical studies*** and have engaged with relevant regulatory authorities to ensure that the Ocaliva label sufficiently reinforces the importance of appropriate dosing in patients with advanced cirrhosis. ***These events and any safety concerns associated with Ocaliva, perceived or real, may adversely affect the successful development and commercialization of our product candidates and lead to a loss of revenues***.

94. The 2019 10-K similarly stated:

> We remain focused on the safety of all of the patients using Ocaliva within and outside of our ongoing clinical studies and have engaged with relevant regulatory authorities to ensure that the Ocaliva label sufficiently reinforces the importance of appropriate dosing in patients with advanced cirrhosis. ***These events, the revised label, any future label changes that may be required by the FDA or other relevant regulatory authorities and any safety concerns associated with Ocaliva, perceived or real, may materially and adversely affect our Ocaliva commercialization efforts and, consequently, our financial condition and results of operations.***

95. The 2019 10-K further stated:

> Additional or unforeseen side effects relating to OCA or any of our other product candidates could arise either during clinical development or, if approved, after the approved product has been marketed. With the approval of Ocaliva for PBC in the United States, Europe and certain of our other target markets, OCA is currently used in an environment that is less rigorously controlled than in clinical studies. If new side effects are found, if known side effects are shown to be more severe than previously observed or if OCA is shown to have other unexpected characteristics, we may need to abandon our development of OCA for PBC, NASH and other potential indications. Furthermore, our commercial sales of Ocaliva for PBC may be materially and adversely affected.

96. The statements in ¶¶91-95 were materially false and/or misleading when made and/or omitted to state material facts necessary to make the statements not misleading, because they failed to disclose that there were several serious adverse events from OCA in PBC patients that were not already cited on Ocaliva's label and that these serious adverse events in patients taking the same drug was a material risk to approval of the NASH NDA.

E. Defendants' False And Misleading Statements Disseminated To The Public On May 11, 2020

97. On May 11, 2020, Intercept issued a press release entitled "Intercept Pharmaceuticals Reports First Quarter 2020 Financial Results, and Provides Business Update." Therein, the Company stated, in relevant part:

> "We have had a busy start to the year here at Intercept," said Mark Pruzanski, M.D., President and Chief Executive Officer of Intercept. "In the first quarter we saw better than anticipated Ocaliva net sales in our PBC business, which were supported by continued strong total prescription trends and modestly higher than expected inventory demand towards the end of the quarter as certain customers responded to the uncertainty of the early COVID-19 period. Like all companies, we are adjusting to the new environment created by the global pandemic, and lam very proud of our team's response. ***We have taken a number of important steps intended to ensure the integrity of our clinical trials, maintain continuity in our supply chain and advance our NASH launch preparation activities***, all while continuing to deliver solid results and protecting the health and safety of our employees. ***We remain very focused on the goal of bringing the first approved therapy to patients with advanced fibrosis due to NASH and expect to be well prepared for our upcoming FDA advisory committee meeting, which is tentatively scheduled for June 9, 2020.***"
>
> ***
>
> Our selling, general and administrative expenses increased to $98.6 million in the first quarter of 2020, up from $77.2 million in the prior year quarter. The increase was primarily driven by organizational growth and additional activities associated with our preparation for the potential approval and commercialization of OCA for liver fibrosis due to NASH.

98. Additionally, during an earnings call with analysts held also on May 11, 2020, Pruzanski stated, in relevant part, in response to a question about recent communications with the FDA:

> And then moving over to the safety side, there's overall exposure that we have. And then the safety topics that are well-known with respect to our drug that are in the literature. Pruritus being one, tolerability and then hepatic or more broadly

> hepatobiliary, and of course, the on-target lipid changes that we know very well. So those would be the anticipated topics there.

99. The same day, Intercept filed its quarterly report on Form 10-Q for the period ended March 31, 2020 (the "1Q20 10-Q"). Regarding safety, the report stated:

> In the course of our post-marketing pharmacovigilance activities, deaths have been reported in PBC patients with moderate or severe hepatic impairment. In an analysis performed by us and in consultation with the FDA, we concluded that certain of these patients were prescribed once daily doses of Ocaliva, which is seven times higher than the recommended weekly dose in such patients. . . . ***We remain focused on the safety of all of the patients using Ocaliva within and outside of our ongoing clinical studies*** and have engaged with relevant regulatory authorities to ensure that the Ocaliva label sufficiently reinforces the importance of appropriate dosing in patients with advanced cirrhosis. ***These events and any safety concerns associated with Ocaliva, perceived or real, may adversely affect the successful development and commercialization of our product candidates and lead to a loss of revenues.***

100. The 1Q20 10-Q similarly stated:

> In the course of our post-marketing pharmacovigilance activities, deaths have been reported in PBC patients with moderate or severe hepatic impairment. In an analysis performed by us and in consultation with the FDA, we concluded that certain of these patients were prescribed once daily doses of Ocaliva, which is seven times higher than the recommended weekly dose in such patients. . . . ***We remain focused on the safety of all of the patients using Ocaliva within and outside of our ongoing clinical studies*** and have engaged with relevant regulatory authorities to ensure that the Ocaliva label sufficiently reinforces the importance of appropriate dosing in patients with advanced cirrhosis. ***These events, the revised label, any future label changes that may be required by the FDA or other relevant regulatory authorities and any safety concerns associated with Ocaliva, perceived or real, may materially and adversely affect our Ocaliva commercialization efforts and, consequently, our financial condition and results of operations.***

101. The 1Q20 10-Q further stated:

> Additional or unforeseen side effects relating to OCA or any of our other product candidates could arise either during clinical development or, if approved, after the approved product has been marketed. With the approval of Ocaliva for PBC in the United States, Europe and certain of our other target markets, OCA is currently used in an environment that is less rigorously controlled than in clinical studies. If new side effects are found, if known side effects are shown to be more severe than previously observed or if OCA is shown to have other unexpected characteristics, we may need to abandon our development of OCA for PBC, NASH and other potential indications. Furthermore, our commercial sales of Ocaliva for PBC may be materially and adversely affected.

102. The statements in ¶¶97-101 were materially false and/or misleading when made and/or omitted to state material facts necessary to make the statements not misleading, because

they failed to disclose that the FDA had informed the Company that the agency had identified the NISS with Ocaliva related to liver disorder and was going to investigate the risk, that this investigation created a substantial, undisclosed risk to Intercept's future revenue from Ocaliva sales to PBC patients and business, and that the serious adverse events that led to this investigation and the investigation itself were material risks to approval of the NASH NDA.

F. Defendants' False And Misleading Statements Disseminated To The Public On May 22, 2020

103. On May 22, 2020, Intercept issued a press release entitled "Intercept Provides Regulatory Update." Therein, the Company stated, in relevant part:

> Intercept Pharmaceuticals, Inc. (Nasdaql1CPT), a biopharmaceutical company focused on the development and commercialization of novel therapeutics to treat progressive non-viral liver diseases, today announced that based on discussions earlier this week, the U.S. Food and Drug Administration (FDA) has notified Intercept that its tentatively scheduled June 9, 2020 advisory committee meeting (AdCom) relating to the company's new drug application (NDA) for obeticholic acid (OCA) for the treatment of liver fibrosis due to nonalcoholic steatohepatitis (NASH) has been postponed. ***The postponement will accommodate the review of additional data requested by the FDA that the company intends to submit within the next week.*** The FDA has indicated that it will reach out to Intercept in the near future with a new proposed AdCom date. Intercept now anticipates that the FDAs review of its NDA will extend beyond the Prescription Drug User Fee Act (PDUFA) target action date of June 26, 2020.
>
> "While this delay was unanticipated, ***following our most recent dialogue with the FDA we believe that the additional data being submitted will be important in facilitating a more informed discussion at the AdCom***," said Mark Pruzanski, M.D., President and Chief Executive Officer of Intercept. "***We remain confident in our NDA submission and look forward to continuing to work with the FDA to bring the first treatment to patients with advanced fibrosis due to NASH***."

104. The statements in ¶103 were materially false and/or misleading when made and/or omitted to state material facts necessary to make the statements not misleading, because they failed to disclose that the FDA had informed the Company that the agency had identified the NISS with Ocaliva related to liver disorder and was going to investigate the risk, that this investigation created a substantial, undisclosed risk to Intercept's future revenue from Ocaliva sales to PBC patients and business, and that the serious adverse events that led to this investigation and the investigation itself were material risks to approval of the NASH NDA.

G. Defendants' False And Misleading Statements Disseminated To The Public On June 29, 2020

105. On June 29, 2020, Intercept issued a press release entitled "Intercept Receives Complete Response Letter from FDA for Obeticholic Acid for the Treatment of Fibrosis Due to NASH." Therein, the Company stated, in relevant part:

> The CRL indicated that, based on the data the FDA has reviewed to date, the Agency has determined that the predicted benefit of OCA based on a surrogate histopathologic endpoint remains uncertain and does not sufficiently outweigh the potential risks to support accelerated approval for the treatment of patients with liver fibrosis due to NASH. The FDA recommends that Intercept submit additional post-interim analysis efficacy and safety data from the ongoing REGENERATE study in support of potential accelerated approval and that the long-term outcomes phase of the study should continue.

106. The same day, the Company held a business update conference call with analysts and investors to discuss the Company's receipt of the CRL for its NASH NDA. During that call, Defendant Pruzanski stated, in relevant part, in response to a question about whether he believed had recently given the FDA pause about the risks of approval:

> On the safety side, the typical known profile of OCA that there is nothing substantively new in terms of safety issue that's arisen or that the agency has pointed to. And so, no, I don't think that there is anything there that's come up that figured into a fundamentally different view about benefit risk. I think that what's new here is the questioning without really substantiation as far as we can tell on the benefit side and what kind of benefit the result on the surrogate -- predefined surrogate that we went on, what kind of benefit that predicts.

107. Moreover, during the same call and in response to a question about whether the FDA mentioned anything about the safety of OCA in recent communications, Pruzanski stated, in relevant part:

> Yes. So, Ritu on the safety side, as I mentioned a couple of minutes ago, the safety issues are consistent with the known profile of OCA. There is nothing substantively new in terms of the safety issues flagged. And frankly, from our point of view, nothing that stands out as a showstopper, right? So we're not talking about something new on the safety side.

108. The statements in ¶¶105-107 were materially false and/or misleading when made and/or omitted to state material facts necessary to make the statements not misleading, because they failed to disclose that the FDA had informed the Company that the agency had identified the NISS with Ocaliva related to liver disorder and was going to investigate the risk, that this

investigation created a substantial, undisclosed risk to Intercept's future revenue from Ocaliva sales to PBC patients and business, and that the serious adverse events that led to this investigation and the investigation itself were material risks to approval of the NASH NDA.

H. Defendants' False And Misleading Statements Disseminated To The Public On August 10, 2020

109. On August 10, 2020, Intercept issued a press release entitled "Intercept Pharmaceuticals Reports Second Quarter 2020 Financial Results, Announces Updates to Financial Guidance and Provides Business Update." Therein, the Company stated, in relevant part:

> "Our PBC business achieved its highest quarterly net sales to date in the second quarter," said Mark Pruzanski, M.D., President and Chief Executive Officer of Intercept. "We plan to continue to invest in our growing PBC business and announced 2020 Ocaliva net sales guidance earlier this morning. We anticipate that our Ocaliva net sales, together with the announced reduction in our 2020 non-GAAP adjusted operating expense guidance, will help to ensure that we are financially well positioned to support the path forward in NASH. In the meantime, we are preparing to meet with the FDA to discuss the basis for resubmission of our NDA seeking accelerated approval of OCA for the treatment of advanced fibrosis due to NASH, and continue to believe that OCA has the potential to become the foundational treatment for these patients. I am encouraged by the outpouring of support we have received from the liver community in recent weeks and we remain committed to our goal of bringing the first therapy to market for patients with this serious condition."

110. Additionally, during an earnings call with analysts held also on August 10, 2020, Pruzanski stated, in relevant part, in response to a question about whether Intercept was considering a strategy to focus on rare liver diseases, such as PBC, in light of the CRL:

> But the thrust of your question is, and I think is important to point out, is the enormous value, I think, of our foundational business and PBC. We just reported, as you know, a record quarter since launch. Business continues to grow and we continue very much to be committed to patients with PBC who have a need and are eligible for Ocaliva treatment worldwide. So we will continue to drive to build that business. And in the unexpected eventuality that you're flagging, we certainly have a great foundational business to continue to build the company up on.

111. Moreover, during the same earnings call, Jerry Durso, the Company's current CEO but then Chief Operating Officer, stated, in relevant part, in response to question about potential expansion into the PBC market:

> We continue to believe and see that the PBC market has good remaining potential for us to access both in the U.S. and in Europe. I think if you look at the growth

> we posted in the first half and the sales guidance despite the disruption that's obviously out there with COVID, it's an indicator that there continues to be patients out there that need to be identified for appropriate therapy. And Ocaliva, within the indication, the confidence that the individual prescribing physicians have as they gain more experience over time leads us to that. So there are more patients. I think the opportunity now with the CRL to really refocus commercially back to PBC as we move in the next period is going to allow us to continue to grow. And we still, again, feel we have a significant opportunity yet in the PBC opportunity

112. The statements in ¶¶109-111 were materially false and/or misleading when made and/or omitted to state material facts necessary to make the statements not misleading, because they failed to disclose that the FDA had informed the Company that the agency had identified the NISS with Ocaliva related to liver disorder and was going to investigate the risk, and that this investigation created a substantial, undisclosed risk to Intercept's future revenue from Ocaliva sales to PBC patients and business.

VI. LOSS CAUSATION

113. During the Class Period, as detailed herein, Defendants made materially false and/or misleading statements and/or omissions. This course of wrongful conduct caused the price of Intercept securities to be artificially inflated. But for Defendants' misrepresentations and/or omissions, Plaintiffs and the other members of the Class would not have purchased Intercept securities or would not have purchased such securities at artificially inflated prices. Later, when Defendants' prior misrepresentations and/or omissions were disclosed to the market, the price of Intercept shares fell significantly as the prior artificial price inflation dissipated. As a result of their purchases and/or acquisition of Intercept securities during the Class Period, Plaintiffs and other members of the Class suffered economic loss, *i.e.*, damages, under the Exchange Act. The timing and magnitude of the decline in the prices of the Company's shares negates any inference that the economic losses and damages suffered by Plaintiffs and the other members of the Class were caused by changed market conditions, macroeconomic factors, or Company-specific facts unrelated to Defendants' wrongful conduct.

114. The truth regarding Intercept was partially revealed, and/or the concealed risks materialized, on or about: May 22, 2020; June 29, 2020; and October 8, 2020. As a direct result

of these partial disclosures, the price of Intercept's stock declined precipitously on heavy trading volume.

115. On May 22, 2020, the Company issued a press release entitled "Intercept Provides Regulatory Update," revealing that the AdCom meeting related to the NDA for Ocaliva for the treatment of NASH had been postponed to "accommodate the review of additional data requested by the FDA that the company intends to submit within the next week." The press release stated, in relevant part:

> Intercept Pharmaceuticals, Inc. (Nasdaq:ICPT), a biopharmaceutical company focused on the development and commercialization of novel therapeutics to treat progressive non-viral liver diseases, today announced that based on discussions earlier this week, the U.S. Food and Drug Administration (FDA) has notified Intercept that its tentatively scheduled June 9, 2020 advisory committee meeting (AdCom) relating to the company's new drug application (NDA) for obeticholic acid (OCA) for the treatment of liver fibrosis due to nonalcoholic steatohepatitis (NASH) has been postponed. The postponement will accommodate the review of additional data requested by the FDA that the company intends to submit within the next week. The FDA has indicated that it will reach out to Intercept in the near future with a new proposed AdCom date. Intercept now anticipates that the FDA's review of its NDA will extend beyond the Prescription Drug User Fee Act (PDUFA) target action date of June 26, 2020.
>
> "While this delay was unanticipated, following our most recent dialogue with the FDA we believe that the additional data being submitted will be important in facilitating a more informed discussion at the AdCom," said Mark Pruzanski, M.D., President and Chief Executive Officer of Intercept. "We remain confident in our NDA submission and look forward to continuing to work with the FDA to bring the first treatment to patients with advanced fibrosis due to NASH."
>
> Intercept previously announced the FDA's acceptance of the NDA and granting of priority review. OCA has received Breakthrough Therapy designation from the FDA for the treatment of NASH patients with liver fibrosis.

116. On this news, the Company's share price fell $11.18, or 12.19%, to close at $80.51 per share on May 22, 2020, on unusually heavy trading volume.

117. The price decline on May 22, 2020 was the result of the nature and extent of defendants' wrongful conduct being partially revealed to investors and the market. *Inter alia*, the disclosure on May 22, 2020 was a partial disclosure in that it was a materialization of a known risk. Specifically, the AdCom meeting for the NDA for NASH was postponed due to, among other things, the additional data that the Company was required to submit. Nevertheless,

Defendants failed to disclose that the additional data had been requested following an ongoing review by the FDA of a newly identified safety signal regarding liver disorder for Ocaliva for the treatment of PBC.

118. On June 29, 2020, the Company issued a press release entitled "Intercept Receives Complete Response Letter from FDA for Obeticholic Acid for the Treatment of Fibrosis Due to NASH." Therein, Intercept disclosed:

> The CRL indicated that, based on the data the FDA has reviewed to date, the Agency has determined that the predicted benefit of OCA based on a surrogate histopathologic endpoint remains uncertain and does not sufficiently outweigh the potential risks to support accelerated approval for the treatment of patients with liver fibrosis due to NASH. The FDA recommends that Intercept submit additional post-interim analysis efficacy and safety data from the ongoing REGENERATE study in support of potential accelerated approval and that the long-term outcomes phase of the study should continue.

119. On this news, the Company's share price fell $30.79, or 39.73%, to close at $46.70 per share on June 29, 2020, on unusually heavy trading volume.

120. The price decline on June 29, 2020 was the result of the nature and extent of defendants' wrongful conduct being partially revealed to investors and the market. *Inter alia*, the disclosure on June 29, 2020 was a partial disclosure in that it was a materialization of a known risk. Specifically, it revealed that the FDA would not approve the NDA for Ocaliva as a treatment for NASH without additional safety and efficacy data sufficient to conclude that the benefits outweighed the potential risks. However, Defendants failed to disclose that potential safety risks identified by the FDA during its ongoing evaluation of Ocaliva as a treatment for PBC raised a material risk that the NDA for NASH would not be approved.

121. On October 8, 2020, STAT News published an article entitled "FDA investigating whether Intercept Pharma drug is tied to potential liver injury risk." The article revealed that, since May 2020, the FDA was investigating Ocaliva for a potential risk of liver disorder in PBC patients and that the probe will likely span 12 months. It questioned: "Did the FDA's liver safety evaluation of Ocaliva, which began in May, contribute to the agency's decision in June to reject the NASH application?" The article further highlighted:

> Intercept has not previously said anything publicly about the FDA examination. Instead, the company chose to disclose the inquiry by adding several new sentences to an existing risk-statement paragraph on the 57th page of its most recent quarterly report filed with the Securities and Exchange Commission. The change was picked up by a health care investor on Twitter earlier this week.

122. On this news, the Company's share price fell $3.30, or 8.05%, to close at $37.69 per share on October 8, 2020, on unusually heavy trading volume.

123. The price decline on October 8, 2020 was the result of the nature and extent of defendants' wrongful conduct being partially revealed to investors and the market. *Inter alia*, the disclosure on October 8, 2020 revealed that the FDA was evaluating a newly identified safety signal regarding liver disorder for Ocaliva.

VII. ADDITIONAL SCIENTER ALLEGATIONS

124. As alleged herein, the Individual Defendants acted with scienter since they knew that the public documents and statements issued or disseminated by Intercept and the Individual Defendants, including in the name of the Company, were materially false and/or misleading; knew that such statements or documents would be issued or disseminated to the investing public; and knowingly or substantially participated or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the federal securities laws. As set forth elsewhere herein in detail, Defendants Pruzanski and Kapadia by virtue of their receipt of information reflecting the true facts regarding Intercept, their control over, and/or receipt and/or modification of Intercept's allegedly materially misleading statements and/or their associations with the Company which made them privy to confidential proprietary information concerning Intercept, participated in the fraudulent scheme alleged herein.

125. Defendants Pruzanski and Kapadia knew or recklessly disregarded the false and misleading nature of the information they caused to be disseminated to the investing public. The fraudulent scheme described herein could not have been perpetuated during the Class Period without the knowledge and complicit or, at least, the reckless disregard of the personnel at the highest level of the Company, including Defendants Pruzanski and Kapadia.

126. The following additional facts give rise to a strong inference that the Defendants acted with scienter.

A. Ocaliva Was Intercept's Sole Drug Candidate And Any Safety Risks Presented By Ocaliva Could Impact Approval Of The NASH NDA

127. The wrongful conduct alleged herein, relating to the safety and approval of Ocaliva, involved Intercept's core operations, and knowledge of the wrongful conduct may therefore be imputed to the Individual Defendants. Specifically, Ocaliva was crucial to the Company's success because it was the sole drug candidate, so the Individual Defendants closely monitored, or should have closely monitored, the safety-related events when Ocaliva was used to treat PBC.

128. As Defendant Pruzanski emphasized during the Q3 2019 earnings call, "the NASH market represents a much larger commercial opportunity" than PBC, so the Individual Defendants knew, or should have known, of risks impacting the approval of Ocaliva for the treatment of NASH. The frequency and severity of these safety-related events when used to treat PBC would foreseeably raise doubts at the FDA regarding the approval of Ocaliva for the treatment of NASH. More specifically, defendant Pruzanski stated during the June 29, 2020 business update call that "the safety issues are consistent with the known profile of OCA," meaning that any safety risks that Ocaliva presented in connection with PBC were reasonably likely to arise when used in connection with NASH.

129. The Individual Defendants were aware of the details of the NASH NDA, as well as the risks impacting approval, because it presented an opportunity for the Company to expand its total addressable market from PBC patients (totaling 290,000 people worldwide) to include NASH patients (totaling 3-5% of the world's population), thus increasing its revenue exponentially. Indeed, after submitting the NDA, Intercept began preparing for a commercial launch that could be executed upon FDA approval. For example, during the Q1 2020 earnings call, Intercept's Chief Operating Officer stated: "Consistent with our objective to be fully ready for launch as early as the PDUFA target action date, we've hired and trained the majority of our

targeted field-based teams across, sales, market access and medical affairs." As a result of the significant investment into the NASH launch and the sizeable market it presented, the Individual Defendants were aware of the potential risks precluding FDA approval of the NASH NDA, including potential safety risks raised by long-term use of Ocaliva as exhibited in PBC patients. Or, if the Company's CEO and CFO were unaware, this ignorance constitutes acting in such a deliberately reckless manner as to constitute a fraud and deceit upon Plaintiffs and other Class members. However, the most reasonable inference from this fact is that the Individual Defendants were aware of the safety risks with Ocaliva that posed a material risk to the approval of the NASH NDA.

B. The Individual Defendants Purported To Be Involved In Communications With The FDA And Prepared A Range Of Topics In Anticipation Of The Adcom

130. The Individual Defendants claimed throughout the Class Period that they had been preparing additional data sets to submit to the FDA in the course of the NDA review and based on their discussions with the FDA. Therefore, they had reason to know that the FDA was concerned with safety risks that Ocaliva presented when used to treat PBC and whether those risks (which were reasonably likely to present when Ocaliva was used to treat NASH since it's the same drug) outweighed the clinical benefit of Ocaliva for the treatment of NASH.

131. For example, during the Q1 2020 earnings call, an analyst asked: "as we approach the AdCom, can [the Individual Defendants] talk about the types of additional updated data sets or analyses [Intercept has] been submitting to the FDA that may emerge in the briefing documents or AdCom discussion? And how overall that's evolved your confidence in OCA's overall benefit risk profile?" In response, defendant Pruzanski assured that "yes, there are additional analyses" and that "We, in totality, only have more confidence, therefore, in the robustness of our data in support of accelerated approval."

132. As a result of these interactions, the Individual Defendants knew as early as May 2020 (if not earlier) that the FDA's review and identification of the NISS for liver disorder in PBC patients presented a material risk that the NASH NDA would not be approved because, as

they had previously admitted, "any safety concern associated with Ocaliva, perceived or real, could negatively impact the drug's sales or its effort to expand use into other types of liver disease."

133. Indeed, the same month that the FDA commenced its investigation of Ocaliva as a potential risk for liver disorder, several analyst reports highlighted Intercept's "constant stream of interactions" with the FDA. For example, in a report published on May 22, 2020, Cantor Fitzgerald analysts stated that the Company "notes that there have been constant stream of interactions generating a ton of data spanning a range of topics including efficacy, safety, benefit/risk." Similarly, Chardan analysts stated in a report issued the same day that "[b]ased on what we have heard from Intercept so far, it appears the company has maintained a dialogue with FDA ahead of the anticipated virtual AdComm, and that this data request may have been born[e] out of that dialogue." Likewise, SVBLeerink analysts noted that "[t]he company indicated that this decision [to submit additional data] follows recent discussions between ICPT and FDA, with both parties reaching the conclusion that additional data should be included in the package submitted to the AdCom panel for review."

134. Moreover, the Individual Defendants had emphasized that they were "prudently preparing" a range of topics in anticipation of the AdCom, including safety risks associated with Ocaliva, and assured that they would "be ready." During the Q4 2019 earnings call, Defendant Pruzanski assured "Planning for an AdCom is a major undertaking, and we are confident that we will be well prepared."

135. The Individual Defendants specifically mentioned the safety risks affecting the NDA. For example, during the Q3 2019 earnings call, defendant Pruzanski stated that "in terms of the focus of interest at that AdCom, it would ultimately go to – across the board to efficacy and safety and overall benefit/risk." He touted that management was "obviously very confident, based on all the data that we've seen, in the favorable benefit-risk profile of OCA at the 25-milligram dose." Defendant Pruzanski even commented specifically about gallstones, which an analyst had raised, and stated that "that particular signal doesn't alter our view of benefit/risk,"

suggesting that he was attuned to the range of possible safety risks as well as their relative impact on the approval of the NDA.

136. Analysts even probed the comparison between PBC and NASH. For example, during the Q4 2019 earnings call, an analyst asked: "What are the biggest questions that you anticipate heading into this panel? And how are you prepared to answer them? And can you just talk maybe how they compare and contrast kind of the expectations for this panel and what you – versus what happened at the PBC panel? Obviously 2 different diseases, but same drug." Defendant Pruzanski responded:

> [W]e're well underway in terms of preparation for this panel. I think the difference from PBC, and we do have that experience, as I mentioned, with a very successful outcome, is at least twofold. One is this is the first drug in a new category. Second, NASH is obviously a much bigger disease and the patients, frankly, that we're targeting with advanced fibrosis are generally sicker, right? They have typically multiple comorbidities.
>
> So we're preparing, I would say, more broadly. We are actively consulting with experts across a range of disciplines, matching the typical NASH patient. I think -- look, no surprises here. What FDA typically puts to a panel like this spans the range of what is required to inform an assessment of benefit-risk of any drug, and that's what we're preparing for.

137. As a result of the Individual Defendants self-proclaimed dialogue with the FDA as well as its exhaustive preparation for the AdCom meeting, the Individual Defendants knew or should have known that Ocaliva presented certain safety risks including liver disorder, that the FDA had identified a NISS with Ocaliva among PBC patients, and that, as a result, there was a material risk to the FDA approval of the NASH NDA.

C. Defendant Pruzanski Profited Handsomely From Selling Intercept Stock At Inflated Prices

138. Defendant Pruzanski took advantage of the artificially inflated price of Intercept stock resulting from the false and/or misleading statements to sell a significant amount of his directly and indirectly owned shares in the weeks following the submission of the NDA.

139. Defendant Pruzanski made the following stock sales during the Class Period:

Transaction Date	Number of Shares	Price Sold	Proceeds Received
11/25/2019	14,563	$100.00	$1,456,300
11/26/2019	35,437	$100.00	$3,543,700
12/26/2019	417	$125.00	$52,125
12/31/2019	100	$125.00	$12,500
Total:	**50,517**		**$5,064,625**

140. These millions of dollars provided a very real incentive for Defendant Pruzanski to omit to disclose the material risks impacting approval of the NASH NDA. Disclosing the truth would have jeopardized Intercept's position as a frontrunner in the NASH market and cost himself the opportunity to sell millions of dollars' worth of personal holdings at inflated prices.

D. Longstanding Executives Directly Involved In The Development And Approval Of Ocaliva Were Removed From Their Positions Following The Company's Receipt Of The CRL

141. Defendant Pruzanski is one of the Company's co-founders in 2002 and served as its CEO from its founding. Following the Class Period, on December 10, 2020, Intercept announced that after 19 years as CEO, Pruzanski would leave the position, effective January 1, 2021. He was replaced by Intercept's Chief Operating Officer, Jerry Durso.

142. Soon thereafter, on February 18, 2021, Intercept's Chief Medical Officer, Jason Campagna, tendered his resignation. Though he had only served in the role since December 2019, he played an important role in the development of Ocaliva for the treatment of NASH because he was the NASH Program Leader at Intercept since 2016.

143. Then, on March 8, 2021, defendant Kapadia resigned as Intercept's CFO, effective March 26, 2021.

144. The most logical inference from the departure of long-serving executives, including the leader who developed and commercialized Ocaliva for PBC, is that they knew (or at the very least deliberately ignored) that the Company's statements omitted to disclose potential safety risks that presented a material risk to the approval of the NASH NDA and which could jeopardize Intercept's sole means of revenue.

VIII. CLASS ACTION ALLEGATIONS

145. Plaintiffs bring this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and 23(b)(3) on behalf of a class consisting of all persons and entities that purchased or otherwise acquired Intercept securities during the Class Period, seeking to pursue remedies under the Exchange Act (the "Class"). Excluded from the Class are Defendants; the officers and directors of the Company, at all relevant times; members of their immediate families and their legal representatives, heirs, successors, or assigns; and any entity in which any of the Defendants have or had a controlling interest.

146. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Intercept securities were actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiffs at this time and can only be ascertained through appropriate discovery, Plaintiffs believe that there are hundreds or thousands of members in the proposed Class. Millions of Intercept shares were traded publicly during the Class Period on the NASDAQ.

147. Plaintiffs' claims are typical of the claims of Class members, who were all similarly affected by Defendants' wrongful conduct in violation of federal securities laws that is complained of herein. Further, Plaintiffs will fairly and adequately protect the interests of Class members and have retained counsel competent and experienced in class and securities litigation. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

a. whether the federal securities laws were violated by Defendants' conduct alleged herein;

b. whether statements made by Defendants to the investing public during the Class Period omitted or misrepresented material facts about the business, operations and prospects of Intercept; and

c. to what extent Class members have sustained damages and the proper measure of damages.

148. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Further, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation makes it impossible for Class members to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

IX. UNDISCLOSED ADVERSE FACTS

149. The market for Intercept's securities was open, well-developed and efficient at all relevant times. As a result of these materially false and/or misleading statements, and/or failures to disclose, Intercept's securities traded at artificially inflated prices during the Class Period. Plaintiffs and other members of the Class purchased or otherwise acquired Intercept's securities relying upon the integrity of the market price of the Company's securities and market information relating to Intercept, and have been damaged thereby.

150. During the Class Period, Defendants materially misled the investing public, thereby inflating the price of Intercept's securities, by publicly issuing false and/or misleading statements and/or omitting to disclose material facts necessary to make Defendants' statements, as set forth herein, not false and/or misleading. Said statements and omissions were materially false and/or misleading in that they failed to disclose material adverse information and/or misrepresented the truth about Intercept's business, operations and prospects as alleged herein.

151. At all relevant times, the material misrepresentations and omissions particularized in this Complaint directly or proximately caused or were a substantial contributing cause of the damages sustained by Plaintiffs and other members of the Class. As described herein, during the Class Period, Defendants made or caused to be made a series of materially false and/or misleading statements about Intercept's business, operations and prospects. These material misstatements and/or omissions had the cause and effect of creating in the market an unrealistically positive assessment of the Company and its business, operations and prospects,

thus causing the Company's securities to be overvalued and artificially inflated at all relevant times. Defendants' materially false and/or misleading statements during the Class Period resulted in Plaintiffs and other members of the Class purchasing the Company's securities at artificially inflated prices, thus causing the damages complained of herein.

X. APPLICABILITY OF THE FRAUD-ON-THE-MARKET AND *AFFILIATED UTE* PRESUMPTIONS OF RELIANCE

152. The market for Intercept's securities was open, well-developed, and efficient at all relevant times. As a result of Defendants' materially false or misleading statements and material omissions, the Company's securities traded at artificially inflated prices during the Class Period. On December 24, 2019, the Company's stock closed at a Class Period high of $124.09 per share. Plaintiffs and other members of the Class purchased or otherwise acquired the Company's securities relying on the integrity of the market price of such securities and on publicly available market information relating to Intercept; Plaintiffs and Class members have been damaged thereby.

153. During the Class Period, the artificial inflation of the value of Intercept's securities was caused by the material misrepresentations and omissions alleged in this Complaint, thereby causing the damages sustained by Plaintiffs and other Class members. As alleged herein, during the Class Period, Defendants made or caused to be made a series of materially false or misleading statements about the Company's business, operations and prospects, causing the price of the Company's securities to be artificially inflated at all relevant times. When the truth was disclosed, it drove down the value of the Company's securities, causing Plaintiffs and other Class members that had purchased the securities at artificially inflated prices to be damaged as a result.

154. At all relevant times, the market for Intercept's securities was efficient for the following reasons, among others:

a. Intercept's stock met the requirements for listing, and it was listed and actively traded on the NASDAQ, highly efficient and automated markets.

b. As a regulated issuer, Intercept filed periodic public reports with the SEC and/or the NASDAQ.

c. Intercept regularly communicated with public investors via established market communication mechanisms, including through regular dissemination of press releases on the national circuits of major newswire services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services.

d. Intercept was followed by securities analysts employed by brokerage firms, who wrote reports about the Company, which reports were distributed to the sales force and certain customers of their respective brokerage firms and were made publicly available.

155. Based on the foregoing, during the Class Period, the market for Intercept securities promptly digested information regarding the Company from all publicly available sources and impounded such information into the price of Intercept securities. Under these circumstances, the market for Intercept securities was efficient during the Class Period and, therefore, investors' purchases of Intercept securities at artificially inflated market prices give rise to a class-wide presumption of reliance under the fraud-on-the-market doctrine.

156. In the alternative, the *Affiliated Ute* presumption of reliance applies to the extent that Defendants' statements during the Class Period involved omissions of material facts.

XI. NO SAFE HARBOR

157. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the statements alleged to be false or misleading herein that relate to then-existing facts and conditions, nor does it apply to any material omissions alleged herein. To the extent that statements alleged to be false or misleading are characterized as forward-looking, the statutory safe harbor does not apply to such statements because they were not sufficiently identified as "forward-looking statements" when made, there were no meaningful cautionary statements identifying important factors that could cause actual results to

differ materially from those in the forward-looking statements, and Defendants had actual knowledge that the forward-looking statements were materially false or misleading at the time each such statement was made.

XII. COUNTS

FIRST COUNT
Violation of Section 10(b) of The Exchange Act and
Rule 10b-5 Promulgated Thereunder Against All Defendants

158. Plaintiffs repeat and reallege each and every allegation set forth above as if fully set forth herein. This claim is asserted against all Defendants.

159. During the Class Period, Defendants carried out a plan, scheme and course of conduct which was intended to and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiffs and other Class members, as alleged herein; and (ii) cause Plaintiffs and other members of the Class to purchase Intercept securities at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, defendants, and each of them, took the actions set forth herein.

160. Defendants (i) employed devices, schemes, and artifices to defraud; (ii) made untrue statements of material fact and/or omitted to state material facts necessary to make the statements not misleading; and (iii) engaged in acts, practices, and a course of business which operated as a fraud and deceit upon the purchasers of the Company's securities in an effort to maintain artificially high market prices for Intercept securities in violation of Section 10(b) of the Exchange Act and Rule 10b-5. All Defendants are sued either as primary participants in the wrongful and illegal conduct charged herein or as controlling persons as alleged below.

161. Defendants, individually and in concert, directly and indirectly, by the use, means or instrumentalities of interstate commerce and/or of the mails, engaged and participated in a continuous course of conduct to conceal adverse material information about Intercept's business, operations and prospects, as specified herein.

162. These Defendants employed devices, schemes and artifices to defraud, while in possession of material adverse nonpublic information and engaged in acts, practices, and a

course of conduct as alleged herein in an effort to assure investors of Intercept's value, performance and continued substantial growth, which included the making of, or the participation in the making of, untrue statements of material facts and/or omitting to state material facts necessary in order to make the statements made about Intercept and its business, operations and prospects, in light of the circumstances under which they were made, not misleading, as set forth more particularly herein, and engaged in transactions, practices and a course of business which operated as a fraud and deceit upon the purchasers of the Company's securities during the Class Period.

163. The Individual Defendants' primary liability, and controlling person liability, arises from the following facts: (i) the Individual Defendants were high level executives and/or directors at the Company during the Class Period and members of the Company's management team or had control thereof; (ii) the Individual Defendants, by virtue of their responsibilities and activities as senior officers and/or directors of the Company, were privy to and participated in the creation, development and reporting of the Company's internal budgets, plans, projections and/or reports; (iii) the Individual Defendants were advised of, and had access to, other members of the Company's management team, internal reports and other data and information about the Company's business, operations and prospects at all relevant times; and (iv) the Individual Defendants were aware of the Company's dissemination of information to the investing public which they knew or recklessly disregarded was materially false and misleading.

164. The Defendants had actual knowledge of the misrepresentations and/or omissions of material facts set forth herein, or acted with reckless disregard for the truth in that they failed to ascertain and to disclose such facts, even though such facts were available to them. Such Defendants' material misrepresentations and/or omissions were done knowingly or recklessly and for the purpose and effect of concealing Intercept business, operations and prospects from the investing public and supporting the artificially inflated price of its securities. As demonstrated by Defendants' overstatements and/or misstatements of the Company's business, operations and prospects throughout the Class Period, Defendants, if they did not have actual

knowledge of the misrepresentations and omissions alleged, were reckless in failing to obtain such knowledge by deliberately refraining from taking those steps necessary to discover whether those statements were false or misleading.

165. As a result of the dissemination of the materially false and/or misleading information and/or failure to disclose material facts, as set forth above, the market price of Intercept securities was artificially inflated during the Class Period. In ignorance of the fact that market prices of the Company's securities were artificially inflated, and relying directly or indirectly on the false and misleading statements made by Defendants, or upon the integrity of the market in which the securities trades, and/or in the absence of material adverse information that was known to or recklessly disregarded by Defendants, but not disclosed in public statements by Defendants during the Class Period, Plaintiffs' and the other members of the Class acquired Intercept securities during the Class Period at artificially high prices and were damaged thereby.

166. At the time of said misrepresentations and/or omissions, Plaintiffs and other members of the Class were ignorant of their falsity, and believed them to be true. Had Plaintiffs and the other members of the Class and the marketplace known the truth regarding Intercept, which were not disclosed by Defendants, Plaintiffs and other members of the Class would not have purchased or otherwise acquired their Intercept securities, or, if they had acquired such securities during the Class Period, they would not have done so at the artificially inflated prices which they paid.

167. By virtue of the foregoing, Defendants have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

168. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs and the other members of the Class suffered damages in connection with their respective purchases and sales of the Company's securities during the Class Period.

SECOND COUNT
Violation of Section 20(a) of the Exchange Act
Against the Individual Defendants

169. Plaintiffs repeat and reallege each and every allegation contained above as if fully set forth herein.

170. The Individual Defendants acted as control persons of Intercept within the meaning of Section 20(a) of the Exchange Act as alleged herein. By virtue of their high-level positions, and their ownership and contractual rights, participation in and/or awareness of the Company's operations and/or intimate knowledge of the false statements filed by the Company with the SEC and disseminated to the investing public, the Individual Defendants had the power to influence and control and did influence and control, directly or indirectly, the decision-making of the Company, including the content and dissemination of the various statements which Plaintiffs contend are false and misleading. The Individual Defendants were provided with or had unlimited access to copies of the Company's reports, press releases, public filings and other statements alleged by Plaintiffs to be misleading prior to and/or shortly after these statements were issued and had the ability to prevent the issuance of the statements or cause the statements to be corrected.

171. In particular, the Individual Defendants had direct and supervisory involvement in the day-to-day operations of the Company and, therefore, is presumed to have had the power to control or influence the particular transactions giving rise to the securities violations as alleged herein, and exercised the same.

172. As set forth above, Intercept and the Individual Defendants each violated Section 10(b) and Rule 10b-5 by their acts and/or omissions as alleged in this Complaint. By virtue of their position as a control person, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act.

173. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs and other members of the Class suffered damages in connection with their purchases of the Company's securities during the Class Period.

XIII. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for relief and judgment, as follows:

(a) Determining that this action is a proper class action under Rule 23 of the Federal Rules of Civil Procedure;

(b) Awarding compensatory damages in favor of Plaintiffs and all other Class members against all Defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;

(c) Awarding Plaintiffs and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and

(d) Such other and further relief as the Court may deem just and proper.

XIV. JURY TRIAL DEMANDED

Plaintiffs hereby demand a trial by jury.

Dated: March 11, 2021

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